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| 10/527,140 | 10/19/2005 | Toshiyuki Hayase | SHIG CPTA1402AU | 9503 |

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| EXAMINER | |
|---|---|
| CWERN, JONATHAN | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/527,140 | HAYASE ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan G. Cwern | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 15 September 2008.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1 and 3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 and 3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

Claims 1 and 3 are objected to because of the following informalities:

In claims 1 and 3, "the ultrasonic beam direction" lacks antecedent basis.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the term "in two dimensions" is confusing. First, it is unclear which value is being referred to as in two dimensions, the computer error, or the blood flow velocity vector obtained by the simulation unit. Furthermore, it is unclear what two dimensions are being referred to, and it is not clear from reading the specification.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. (US 7191110) in view of Okada et al. (US 6673020) and Kamm et al. (US 6117087) or Cawlfield (US 6088630) or Hayase et al. ("State Estimator of Flow as an Integrated Computational Method with the Feedback of Online Experimental Measurement", Transactions of the ASME, J. Fluids Eng., Vol. 119 (1997), pp. 814-822).

Charbel et al. show, a blood flow visualizing diagnostic apparatus characterized by having: an analysis processing unit which obtains a blood vessel shape (measuring blood vessels, column 13, line 10-50; also column 17, lines 65-67) and a blood flow velocity (measuring blood velocity, column 15, line 45-column 16, line 30; also column 18, lines 1-2 where blood flow constitutes blood velocity) in the blood vessel by the received signal; a simulation unit which sets computational lattices on the basis of the blood vessel shape obtained by said analysis processing unit to simulate the blood flow velocity and a pressure distribution (the polygonal mesh iso-surface can be considered

a lattice or the cube could also be considered a lattice, it is generated based on the shape of the blood vessel, and is used to simulate the velocity and pressure, column 14, lines 5-column 18, line 6); a feedback unit which computes an error between the blood flow velocity obtained by said analysis processing unit and the blood flow velocity obtained by said simulation unit to feed back the error to said simulation unit (the actual data is used to update the simulated model based on the specific patient data, the actual data is fed back to the model and used to adjust the model, although the word “error” is not specifically used, the adjusting of the model based on patient data can be taken to mean that any error between the simulated model and the actual patient data is corrected, column 17, 55-column 18, line 5); and a display unit which displays the blood flow velocity and the pressure distribution output from said simulation unit after the feedback (column 16, lines 30-45). Also, the feedback unit performs the feedback to a sufficiently large number of representative points which are distributed over the blood flow domain in said computational lattices (A “sufficient” number of points are a number of points that are adequate to complete the task, which in this case is generating a customized patient model. Because the obtained result is in fact a model customized to the patient, a “sufficient” number of points must have been adjusted to achieve a customized patient model, column 17, line 55-column 18, line 5); and using ultrasound to measure the blood velocity (column 16, lines 20-25). Charbel et al. fail to show using ultrasound to measure the shape of the blood vessels, the blood velocity, and the blood pressure. Also, Charbel et al. fail to show calculating a difference between real and simulated values.

Okada et al. disclose an ultrasonic diagnostic apparatus. Okada et al. teach, an ultrasonic measurement unit which emits an ultrasonic signal toward a blood vessel inside a human body to receive the reflected ultrasonic signal (using ultrasound to obtain the size of blood vessels, the velocity of the blood, and the blood pressure, column 2, line 60-column 4, line 60).

Kamm et al. disclose a method and apparatus for noninvasive assessment of a subject's cardiovascular system. Kamm et al. teach that computed features (simulated) can be compared to values obtained from experimental measurements (actual) and a measure of the error or difference between them can be obtained. This difference value can be used to modify the simulated values until the error is sufficiently reduced (column 17, lines 48-64 and Figure 8).

Cawlfield discloses an automatic control system for unit operation. Cawlfield teaches that real values can be compared to simulated values and the difference can be used to update the simulation (column 7, lines 40-46).

Hayase et al. '97 disclose an estimator of flow with feedback of experimental measurement. Hayase et al. '97 teach that a difference between the simulated and experimental values is calculated and fed back to modify the simulation (page 816)

It would have been obvious to one of ordinary skill in the art, at the time the invention as made, to have used ultrasound to measure the shape of the blood vessels, the blood velocity, and the blood pressure as taught by Okada et al., in the system of Charbel et al., with the motivation that ultrasound provides for a suitable and non-invasive imaging means to image blood vessels. Charbel et al. does in fact use Doppler

in their blood flow measurements as well, and while no specific mention is made of using ultrasound to obtain the vessel shape, one of ordinary skill in the art would know that ultrasound imaging provides a suitable means to image blood vessels. In addition, a vector can be considered a two-dimensional value, and so as Okada et al. obtain blood velocity vectors, any related calculations would involve two dimensions. There is a reasonable expectation of success to combine these references, because both are related to measuring blood vessel shape, blood velocity, and blood pressure in a patient.

While Charbel et al. show that the actual blood flow can be used to customize the model to the actual patient, they do not go into specific details of how this is accomplished. Computing the difference between real and simulated values, and using the difference to update a simulation is old and well known across a wide variety of arts. Kamm et al., Cawlfield, and Hayase et al. '97 are three examples of using such a technique. It would have been obvious to one of ordinary skill in the art, to have compared the difference between real and simulated values and used the difference to update the simulation as taught by Kamm et al. or Cawlfield or Hayase et al. '97, to have customized the model of the patient with actual blood flow values in the combined system of Charbel et al. and Okada et al.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al. (US 7191110) in view of Okada et al. (US 6673020) Kamm et al. (US 6117087) or Cawlfield (US 6088630) or Hayase et al. ("State Estimator of Flow as an Integrated

Computational Method with the Feedback of Online Experimental Measurement", Transactions of the ASME, J. Fluids Eng., Vol. 119 (1997), pp. 814-822) as applied to claim 1 above, and further in view of Hayase et al. ("Numerical Realization of Flow Field by Integrating Computation and Measurement, Proceedings of $5^{th}$ World Congress on Computational Mechanics, Vienna, Austria, July 7-12 (2002)).

Hayase et al. '02 disclose a numerical realization of flow field. Hayase et al. '02 teach a similar equation where the Navier-Stokes equation includes a component f, the body force corresponding to the feedback signal (page 4). There is a similar equation to claim 3 where the body force is calculated by multiplying a negative value of the feedback gain with the pressure components (page 5). One of ordinary skill in the art calculating velocity of blood could have substituted appropriate values for blood flow as opposed to the pressure.

It would have been obvious to one of ordinary skill in the art, to have computed the feedback component as taught by Hayase et al. '02, in the combined system of Charbel et al., Okada et al, and Kamm et al. or Cawlfield or Hayase et al. '97. Charbel et al. show that actual values of blood flow can be used to update a simulation model. In the absence of any criticality or unexpected result, it would be an obvious design choice to have performed the calculations another way, such as by normalizing the beam direction.

### ***Response to Arguments***

Applicant's arguments filed 9/15/08 have been fully considered but they are not persuasive.

In regards to applicant's arguments regarding two dimensions, examiner respectfully disagrees. First, it is unclear what is meant by the term in claim 1, and a 112 second paragraph rejection has thus been given. Applicant's explanation in the remarks is unclear. Applicant refers to pages 11-12 and then page 14 in the explanation. However, the term "two dimensional" is only found on page 11. It is not clear how the cited passage from page 14 relates to the passage from pages 11-12. It is unclear what section of page 14 corresponds to "two dimensional". Therefore, it is unclear how the current invention distinguishes over the prior art. It appears that the conventional simulation described in the specification also utilizes x and y velocity vector components in the calculation, if these are the two dimensions being referred to by the term "two dimensions". If this is not the case, then it has not been explained clearly enough in the specification or in the applicant's arguments.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regards to applicant's arguments regarding "obvious design choice", examiner respectfully disagrees. In the **absence of any criticality or unexpected result**, it

would be obvious for one of ordinary skill in the art to perform the calculations in another way. Applicant has not provided any such criticality or unexpected results. Applicant's chart is confusing and does not overcome this problem. It is unclear what information is contained in this chart or its related discussion which shows a criticality or unexpected result using the equation of applicant's invention. In addition, the chart does not appear to contain actual facts, as on page 10 applicant writes, "in the opinion of the inventor it makes sense to regard aspects in different blocks in the same category". The inventor's opinion is not a showing of any such criticality or unexpected result. Applicant should provide evidence that the equation of claim 3 yields some criticality or unexpected result over any other type of calculation to demonstrate that this would not be an obvious design choice.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737